K002992

AUG 1 5 2001

510(k) SUMMARY

as required per 807.92(c)

1. Submitters Name, Address:

Medtronic Functional Diagnostics A/S
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Contact person for this submission: Ms. Tove Kjaer
Date submission was prepared: September 21, 2000

2. Trade Name, Common Name and Classification Name:

A. Trade Name: Disposable Hypodermic Needle Electrode

B. Classification Name: Diagnostic electromyography needle electrode

C. Common Name, Class and regulation Number:

Common Name	Medtronic Code		Class	Regulation number
Disposable Hypodermic Needle Electrode, DHF 25	9013S0421		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 25	9013S0431		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 37	9013S0441		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 50	9013S0451		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 75	9013S0461		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHF 25	1013S0421	Private labeled	II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 25	1013S0431		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 37	1013S0441		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 50	1013S0451		II	21CFR 890.1385
Disposable Hypodermic Needle Electrode, DHN 75	1013S0461		II	21CFR 890.1385

1. Predicate Device Identification:

The new Disposable Hypodermic Needle Electrodes are substantial equivalent to the previously marketed TECA Myoject Disposable Needle Electrodes, which were previously determined by the FDA to be substantial equivalent November 20, 1997, K 973444

2. Device Description:

The monopolar Disposable Hypodermic Needle Electrode is designed for single use only. It consists of a stainless steel cannula electrically insulated with a special PTFE coating, except for the face bevel and the inner surface of the tube. The PTFE coating is to ensure minimal friction between the needle and the tissue, and to ensure electrical insulation on the entire cannula, except for the bevel. A Luer – Lock fitting together with a wire with connector to an extension cable, has been attached to the cannula. This cable will enable the electrical signal to be transferred to a stimulating or recording device.

The sterile electrodes are individually sealed in a hygienic and practical peel-pouch ready for use. The electrodes are delivered in boxes with 12 or 100 electrodes.

5. Intended Use:

The Disposable Hypodermic Needle Electrode is intended to be used for injection of a drug into a muscle of the human body, while recording EMG (electromyography) activity. The electrode with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery.

1. The drug used will be the choice of the physician
2. The drug used should be BOTOX® Botulinum Toxin A. (privately labeled)

Note: There will not be delivered any medicinal drug from Medtronic Functional Diagnostics A/S.

Intended Patient Population:
The Disposable Needle Electrode is intended to be used on adults and pediatric patients.

6 Table of Device Similarities and Differences to Predicate Device:

Comparison of similarities and differences to predicate device

Manufacturer	**Medelec, Inc.** D.B.A. TECA CORP.	**Medtronic Functional Diagnostics A/S**	**Comments to differences**
510(k) number	**Predicate devices** TECA Myoject Disposable Needle Electrode **- K 973444**	**Modified Device** Disposable Hypodermic Needle Electrode. 9013S0421 – 9013S0461 (Medtronic Functional Diagnostics) 1013S0421 – 1013S0461 (Private Labeling) **- K TBD**	
Intended Use / Indication of Use	The disposable hypodermic monopolar needles are FOR SINGLE USE ONLY in electromyography (EMG) in situations wherein it is desired to insert an electrode, in the form of a probe, into a patient to locate a particular muscle and then inject a medication into that muscle. The hypodermic needle with an open lumen is designed for muscle stimulation, motor unit action potential recording and drug delivery. Once the physician is satisfied with the location, he/she injects a drug therein via the lumen of the needle.	The Disposable Hypodermic Needle Electrode is intended to be used for injection of a drug into the muscles of the human body while recording EMG activity. The electrode, with an open lumen, is designed for muscle stimulation, motor unit action potential recording and drug delivery. **1.The drug used will be the choice of the physician.** **2. The drug used should be Botox® Botulinum Toxin type A.**	Same, but the Medtronic version is more precise and simple. The product will be sold under two "indications for use" statements. The differences between these two statements are the last two sentences in the statement, as areindicated in bold.

Intended Populations	Not defined.	Children to Adults	--
Sterilization	Gamma Irradiation (R)	Ethylene Oxide (EO)	Both types can be used as a sterilization method. We have chosen EO, because this method doesn't have any effect on the PTFE.
SAL level	10^{-6}	10^{-6}	--
Biocompatibility	Not defined.	In accordance with ISO 10993.	We have defined the biocompatibility in accordance with the standard, because the product is in contact with tissue and body fluids for less than 24 hours.
Packaging	Secondary package: 10 pieces individually blister packed electrodes in each box. Alternative secondary package: 4 pieces individually blister packed electrodes in each box.	12 and/or 100 pieces individually blister packed electrodes in each box.	
Uses	Single Use Only	Single Use Only	--
Offered Sizes	25mm x 30G 25mm x 27G 37mm x 26G 37mm x 27G 50mm x 25G 50mm x 22G 75mm x 22G 100mm x 22G	25mm x 30G 25mm x 27G 37mm x 27G 50mm x 27G 75mm x 23G	We have chosen the listed sizes, because they are covering our customers' demand.
Shelf-life (Expiry date)	The product remains sterile as long as the seal and the pouch remain undamaged or	Four years in a pouch as long as the seal and the pouch remain undamaged or unopened.	The four years have been justified by validation.

	unopened.		
Electrode cable	Is integrated into the electrode	Is integrated into the electrode	--
Materials – Needle shaft	Stainless Steel AISI 304	Stainless Steel AISI 304	--
Materials – Needle head (hub)	Polypropylene – Himont SR-001 compounded.	Polyethylene (PE-LD), medical grade	As cleared in K990375
Materials – coating	PTFE (Whitford)	Whitford PTFE coat, Xylan 8400/3349	
Protection tube	Polypropylene – Himont SR-001 compounded.	Polyethylene (PE-HD), medical grade	
Connection	14 and 26 inches wire integrated into the electrode	24 inches PVC wire integrated into the electrode.	We have chosen a 24 inches wire, because that is covering our customers demand.
Connector	1.5 mm. safety connector.	1.5 mm. safety connector.	--
Mechanical pull strength	Not defined.	40 N	We have chosen 40N, because we then know, that the product cannot be pulled apart.
Needle grind angle	10-20 Degrees conical	Ten degrees conical	--
Recording area	The tip is exposed only in the vicinity of the facets of the point (0,25 sqmm).	The tip is exposed only in the vicinity of the facets of the point (0,25 sqmm).	--
Peel pouch	Tyvek/Mylar	Tyvek	--

The changes in the new device does not effect any safety or efficacy concerns.

7. Assessment of Non-clinical Performance Data for Equivalence:

Verification results show that the enhanced device performs as its predicate device.

8. Assessment of Clinical Performance Data for Equivalence:

Clinical investigation has not been performed.

9. Biocompatibility:

The following biocompatibility tests have been performed :

- In Vitro Cytotoxicity Test (USP 23/ISO 10993-5 Elution Test)
- Intracutaneous Test performed according to the method described in ISO 10993-10:1995
- Test for Delayed Contact Hypersensitivity using the Guinea Pig Maximization Test.

The result of these tests showed no signs of toxicity.

10. Sterilization:
The needles are sterilized with ETO at a vendor sterilization plant, Maersk Medical A/S.

It is concluded that the process consistently will comply with predetermined specifications. The specified requirements for sterility (EN 556) are met.

11. Standards and Guidances:
All the performed biocompatibility tests have been performed in accordance with the following standards:

- ISO 10993-1 – Biological evaluation of medical devices – part 1: Guidance on selection of tests.
- ISO 10993-10:1995 - Biological evaluation of medical devices-part 10: Tests for irritation and sensitization
- USP 23 / ISO 10993-5 Elution test
- EN 45001

The products are developed and manufactured in accordance with the following standards:

- EN 46001
- ISO 9001

- EN 550 (ETO sterilization and validation)
- EN 556 (Sterilization level)
- EN 1707 (Luer-lock connections)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 5 2001

Ms. Tove Kjaer
Regulatory Affairs Specialist
Medtronic Functional Diagnostics A/S
Tonsbakken 16-18
DK-2740 Skovlunde
Denmark

Re: K002992
Trade Name: Disposable Hypodermic Needle Electrode, Models 9013S0421, 9013S0431, 9013S0441, 9013S0451, 9013S0461, 1013S0421, 1013S0431, 1013S0441, 1013S0451, 1013S0461
Regulation Number: 890.1385, 882.1350, 880.5570
Regulation Name:
Regulatory Class: II
Product Code: IKT, GXZ, FMI
Dated: May 9, 2001
Received: May 17, 2001

Dear Ms. Kjaer:

This letter corrects our substantially equivalent letter of August 15, 2001 regarding the incomplete first page.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K002992

Device Name: **Disposable Hypodermic Needle Electrode**

Indications for Use:

The Botox® Injection Needle may be used for injection of Botox® - Botulinum Toxin Type A into a muscle for trating Strabismus, Blepharospasm and Cervical Dystonia while recording EMG (electromyography) activity. The electrode with an open lumen is designed for muscle stimulation, EMG recording and medicament delivery.

MRI Compatibility Statement:

The Disposable Hypodermic Needle Electrode is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K002992